



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

08/116,873 09/03/93 SUTCLIFFE G SCRF32.0DIVI

SCHEINER, EXAMINER

18N1/0430

WELSH AND KATZ, LTD.
120 SOUTH RIVERSIDE PLAZA
22ND FLOOR
CHICAGO, ILLINOIS 60606E

ART UNIT	PAPER NUMBER
----------	--------------

1813

DATE MAILED:

04/30/96

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Serial Number: 08/116,873

-2-

Art Unit: 1813



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 13

Serial Number: 08/116,873
Filing Date: September 3, 1993
Appellant(s): Gregor J. Sutcliffe

MAILED

APR 29 1996

GROUP 1800

Edward P. Gamson
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed
December 13, 1995.

(1) *Status of claims.*

The statement of the status of claims contained in the brief
is correct.

This appeal involves claims 26-30, 32, and 33.

(2) *Status of Amendments After Final.*

The appellants' statement of the status of amendments after
final rejection contained in the brief is correct.

(3) *Summary of invention.*

The summary of invention contained in the brief is correct.

Art Unit: 1813

(4) *Issues.*

The appellant's statement of the issues in the brief is correct.

(5) *Grouping of claims.*

Appellant states that the appealed claims stand or fall together.

(6) *Claims appealed.*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(7) *Prior Art of record.*

No prior art are relied upon by the examiner in the rejection of claims under appeal.

(8) *New prior art.*

No new prior art has been applied in this examiner's answer.

(9) *Grounds of rejection.*

The following ground of rejection are applicable to the appealed claims.

Claims 26-30, 32, and 33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26-30, 32, and 33 are vague and indefinite since the extent of subject matter to which the exclusionary right granted by patent is intended to apply cannot be determined. That is,

Art Unit: 1813

the claims read on so many DNAs (or mRNAs) that one cannot determine that which is intended. Moreover, it is not possible for the public to determine from the claims what they comprehend since they require explanations extraneous to both the specification and the claims. The claims have not been drafted with a reasonable degree of particularity since one cannot determine what is intended by "having about 500 to about 1800 nucleotide bases that is complementary to cytoplasmic messenger RNA of a mammal that is present in brain cells...." What is the structure of that which is claimed? That is, these claimed nucleic acids have not been defined by structure since characterization (sequence) results have not been set forth and the intended functions of the claimed compositions are unclear. That is, the disclosure in addition to DNA and mRNA, is directed to polypeptides requiring a structural genetic sequence of about 100 bases. What are the sequences of the vast number of DNAs or mRNAs which ultimately encode the "neuroactive proteinoids" mentioned in the specification? The characterization (sequence) of DNAs is critical since all DNAs are made up of the same four nucleotide bases. That is, phenotype and phenotypic variation depend on the order and content of the bases which make up the DNAs since the different types of bases are fixed and limited. A potential infringer having in his possession a sequence (of about 1 Kb) of a DNA or (mRNA) obtained from mammalian brain cells but

Art Unit: 1813

not found in the cells of the liver, kidney, gut, lung, heart or skeletal muscle of the same species would be unable to determine whether or not his DNA species infringes appellant's claims.

Attention is directed to Ex parte Tanksley (26 USPQ2d 1384) wherein the Board noted that, under 35 USC 112, second paragraph, the claims must be so definite as to allow their comparison with the available art and must also make it possible for the public to determine from the claims what it is they comprehend. Only claims limited to the particular nucleic acid sequences as represented by the instant Figures are so definite.

The rejection under the first paragraph of 35 U.S.C. § 112 has been withdrawn.

(10) *New ground of rejection.*

This Examiner's Answer does not contain any new ground of rejection.

(11) *Response to argument.*

With regard to the rejection under the second paragraph of 35 U.S.C. 112, appellant believes and argues that a skilled worker would readily understand the claim language since the source and length of the claimed DNA (or cytoplasmic mRNA) is definite. Appellant argues that structure of the DNAs need not be recited since the Board in Tanksley noted on reconsideration that one could claim the DNAs in question by "base sequence...and/or function." Appellant states that such a

Art Unit: 1813

function has been asserted along with several base sequences and no more is required under Tanksley.

The examiner contends that definite claim language is important for at least two reasons. First, a member of the public (Public domain) must be able to understand what is encompassed by the claims (exclusionary rights) for potential infringement purposes. In this case, a procedure by which a possible infringer could determine if he was in fact infringing appears to be extremely burdensome. Essentially, applicant claims all possible isolated DNA (or mRNA) having a length which falls within a range that is complementary to cytoplasmic mammalian RNA that is present in brain, but not liver, kidney, gut, lung, heart, or skeletal muscle of the same species, wherein the messenger is capable of encoding a neuroactive proteinoid. Second, the claims must be drafted in a definite manner in order that the subject matter may be reasonably compared with the prior art. In this art, it is the actual structure of the composition which is critical for distinguishing one DNA from another since all DNAs are made up of the same four bases regardless of the source. It has been indicated in several prior decisions that claims may be too indefinite to be examined with respect to the prior art. It is clear that determining anticipation in the present case would involve precisely the type of "speculation" proscribed by the decision in *In re Steele*. That is, in *In re*

Serial Number: 08/116,873

-7-


Art Unit: 1813

Steele, 305 F.2d 859, 134 USPQ 292 (CCPA 1962), the court pointed out that before the claimed subject matter could properly be compared to the prior art, it was essential to know what in fact the claims did cover. Appellant does disclose structure of some DNAs. However, the structures are not set forth in the claims. Also, the functions of the DNAs (or mRNAs) as claimed have not been set forth as asserted by appellant. Moreover, in Amgen v Chugai 18 USPQ2d 1017, conception of a chemical compound requires that the inventor be able to define said compound so as to distinguish it from other materials, and to describe how to obtain it, rather than simply defining it solely by its principal biological property. Instant claims are similarly drawn to complex chemical compounds and a detailed constitution (structure) of the genes must be set forth so as to distinguish them from other materials.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,


Laurie Scheiner/LAS


CHRISTINE M. NUCKER
SUPERVISORY PATENT EXAMINER
GROUP 180
